Test Type: 26-WEEK

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/23/2014 AVERAGE SEVERITY GRADES[b]

Test Compound: TRANSGENIC LECM (COCONUT OIL DIETHANOLAMINE)

Species/Strain: Mouse/P53(C57BL/6)

CAS Number: 68603-42-9

Lab: ILS

Time Report Requested: 12:03:00

First Dose M/F: NA / NA

C Number: C55312

Lock Date: 08/21/1997

Cage Range: ΑII

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Both

PWG Approval Date NONE

Species/Strain: Mouse/P53(C57BL/6)

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Time Report Requested: 12:03:00

First Dose M/F: NA / NA

Lab: ILS

P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice	1	1		1
Survivors				
Terminal Sacrifice	9	9	10	9
Animals Examined Microscopically	10			9
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(9)
Centrilobular, Vacuolization Cytoplasmic	1 [1.0]			
Infiltration Cellular, Mixed Cell	3 [1.0]			
Infiltration Cellular, Mononuclear Cl	1 [1.0]			3 [1.0]
Midzonal, Hypertrophy	7 [1.0]			9 [1.0]
Vacuolization Cytoplasmic	1 [1.0]			
Salivary Glands	(10)	(0)	(0)	(9)
Artery, Submandibul GI, Inflammation	1 [3.0]			
Submandibul GI, Infiltration Cellular, Lymphocyte	8 [1.3]			8 [1.3]
Stomach, Forestomach	(10)	(0)	(0)	(9)
Stomach, Glandular	(10)	(0)	(0)	(9)
Artery, Inflammation	1 [2.0]			
Cyst	1 [1.0]			2 [1.0]
Inflammation, Suppurative				1 [1.0]
Mineralization				1 [1.0]
CARDIOVASCULAR SYSTEM None				
ENDOCRINE SYSTEM				

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Test Type: 26-WEEK **Route: SKIN APPLICATION**

Test Compound: TRANSGENIC LECM (COCONUT OIL DIETHANOLAMINE)

Species/Strain: Mouse/P53(C57BL/6)

CAS Number: 68603-42-9

Time Report Requested: 12:03:00

First Dose M/F: NA / NA

Lab: ILS

P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Accessory Adrenal Cortical Nodule				1 [2.0]
Capsule, Hyperplasia				3 [1.0]
Degeneration, Fatty	8 [1.0]			7 [1.1]
Hypertrophy	1 [2.0]			1 [3.0]
Adrenal Medulla	(8)	(0)	(0)	(7)
Pituitary Gland	(9)	(0)	(0)	(8)
Pars Distalis, Cyst	1 [1.0]			1 [1.0]
Thyroid Gland	(10)	(0)	(0)	(9)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(8)
Hyperplasia	1 [3.0]			
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	4 [2.8]			3 [2.0]
Thymus	(9)	(0)	(0)	(9)
Cyst	4 [1.3]			4 [1.0]
INTEGUMENTARY SYSTEM				
Skin	(10)	(0)	(0)	(9)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				

RESPIRATORY SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: 26-WEEK

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Route: SKIN APPLICATION Species/Strain: Mouse/P53(C57BL/6) Test Compound: TRANSGENIC LECM (COCONUT OIL DIETHANOLAMINE)

CAS Number: 68603-42-9

Time Report Requested: 12:03:00

First Dose M/F: NA / NA

Lab: ILS

	•				
P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG	
Lung	(10)	(0)	(0)	(9)	
Congestion				1 [1.0]	
Infiltration Cellular, Lymphocyte	2 [1.0]			2 [1.5]	
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
Kidney	(10)	(0)	(0)	(9)	
Artery, Inflammation	1 [2.0]				
Congestion	2 [1.0]				
Infiltration Cellular, Lymphocyte	1 [1.0]			2 [1.5]	
Infiltration Cellular, Mononuclear Cl				1 [1.0]	
Nephropathy	4 [1.0]			3 [1.0]	

^{***}END OF MALE DATA***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

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First Dose M/F: NA / NA

Lab: ILS

P53(C57BL/6) Mouse FEMALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Disposition Summary				,
Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice	1			
Survivors				
Terminal Sacrifice	9	10	10	9
Missing				1
Animals Examined Microscopically	10			9
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(9)
Infiltration Cellular, Lymphocyte	2 [2.0]			
Infiltration Cellular, Mixed Cell	3 [1.0]			4 [1.0]
Infiltration Cellular, Mononuclear Cl	3 [1.0]			1 [1.0]
Midzonal, Hypertrophy	1 [1.0]			
Necrosis	1 [3.0]			
Salivary Glands	(10)	(0)	(0)	(9)
Submandibul GI, Infiltration Cellular, Lymphocyte	3 [2.3]			5 [1.2]
Submandibul GI, Infiltration Cellular, Plasma Cell	2 [1.0]			
Stomach, Forestomach	(10)	(0)	(0)	(9)
Hyperplasia	1 [1.0]			
Stomach, Glandular	(10)	(0)	(0)	(9)
Cyst	3 [1.0]			3 [1.0]
Inflammation, Suppurative				1 [2.0]

ENDOCRINE SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

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CAS Number: 68603-42-9

Time Report Requested: 12:03:00

First Dose M/F: NA / NA

Lab: ILS

P53(C57BL/6) Mouse FEMALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Adrenal Cortex	(10)	(0)	(0)	(8)
Capsule, Hyperplasia	9 [1.0]			7 [1.3]
Degeneration, Fatty	7 [1.0]			4 [1.0]
Adrenal Medulla	(10)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(6)
Pars Distalis, Cyst	1 [1.0]			
Thyroid Gland	(9)	(0)	(0)	(9)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Uterus	(1)	(0)	(0)	(0)
Hyperplasia, Cystic	1 [3.0]			
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(8)
Hyperplasia	3 [2.0]	, ,	, ,	2 [2.0]
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	6 [2.3]	, ,	, ,	5 [2.2]
Thymus	(9)	(0)	(0)	(9)
Cyst	3 [1.3]			5 [1.0]
INTEGUMENTARY SYSTEM				
Mammary Gland	(10)	(0)	(0)	(4)
Skin	(10)	(0)	(0)	(9)

NERVOUS SYSTEM None

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Lab: ILS

P53(C57BL/6) Mouse FEMALE	0 MG	2.5 MG	5.0 MG	7.5 MG
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(9)
Infiltration Cellular, Histiocyte	1 [1.0]			6 [1.0]
Infiltration Cellular, Lymphocyte	3 [1.3]			3 [1.0]
Infiltration Cellular, Mononuclear Cl	1 [1.0]			
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(9)
Casts Protein	2 [1.0]			
Glomerulus, Inflammation				1 [3.0]
Infiltration Cellular, Lymphocyte	3 [1.3]			1 [2.0]

^{**} END OF REPORT **

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)